

REMARKS

The final Office Action dated November 9, 2007 ("Office Action"), has been carefully reviewed and considered. Paragraphs [0035], at page 8 and [0104], at page 22 of the originally-filed specification have been amended to correct typographical errors. No new matter has been added.

Claims 1-38 are pending. Claim 1 has been amended to further clarify the embodiments claimed in claim 1 and recites, *inter alia*, wherein the active cushioning component is a bead, granule, particle or pellet. Support for amended claim 1 can be found throughout the originally-filed specification, for example at page 8, paragraph [0036] and page 16, paragraph [0085]. No new matter has been added and Applicants believe that such an amendment does not change the scope of claim 1. Claims 12-38 have been withdrawn.

Entry of the above amendments and following remarks and reconsideration of the present application are respectfully requested.

I. DOUBLE PATENTING REJECTION

Claims 1-11 are rejected on the ground of nonstatutory, obviousness-type double patenting as allegedly being unpatentable over claims 16-30 of U.S. Patent No. 5,780,055 to Habib *et al.* ("Habib"). Applicants disagree. For the reasons discussed below, Applicants believe that claims 1-11 are patentably distinct from claims 16-30 of Habib. Therefore, this rejection should be withdrawn.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 102(b)

A. Claims 1-3 And 5-11 Are Patentable Over Habib.

Claims 1-3 and 5-11 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Habib.

Habib discloses placebo cushioning beads that can be combined with biologically active ingredient-loaded beads to form tablets (col. 30, *ll.* 31-38 and col. 45, *ll.* 59-62). However, the placebo cushioning beads of Habib do not contain a biologically active ingredient and the ingredient-loaded beads of Habib do not contain a cushioning component.

Though Applicants disagree with the Examiner's rejection, claim 1 has been amended to recite a compressible dosage form that includes *inter alia*, an active cushioning component wherein the active cushioning component is a bead, granule, particle or pellet, which includes a cushioning component and a biologically active ingredient. Since the beads disclosed in Habib do not contain a cushioning component and a biologically active ingredient, Habib does not teach or suggest an active cushioning component, such as an active cushioning bead, granule, particle or pellet that includes a cushioning component and a biologically active ingredient. Therefore, Applicants believe that claim 1 is patentable over Habib.

Additionally, claims 2-3 and 5-11 depend from claim 1 and include all the recitations of claim 1. Thus, Applicants believe claims 2-3 and 5-11 are also patentable over Habib. Therefore, the Applicants respectfully request that this rejection be withdrawn and claims 1-3 and 5-11 be allowed.

**B. Claims 1-10 Are Patentable Over U.S. Patent
No. 6,254,891 To Anaebonam *et al.***

Claims 1-10 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,254,891 to Anaebonam *et al.* ("Anaebonam").

Anaebonam discloses extended release compositions that include a blend of immediate release acetaminophen particles, controlled release acetaminophen particles and, optionally, placebo particles (col. 3, *l.* 66 to col. 4, *l.* 5 and col. 6, *ll.* 60-63). The placebo particles disclosed in Anaebonam, do not include a cushioning component comprising a highly-compactable filler, nor do they include a biologically active ingredient. Additionally, the acetaminophen controlled release and immediate release particles disclosed in Anaebonam do not include a cushioning component comprising a highly-compactable filler.

Though Applicants disagree with the Examiner's rejection, claim 1 has been amended to recite a compressible dosage form that includes *inter alia*, an active cushioning component wherein the active cushioning component is a bead, granule, particle or pellet, which includes a cushioning component and a biologically active ingredient. Since the particles disclosed in Anaebonam do not include a cushioning component comprising a highly-compactable filler and a biologically active ingredient, Anaebonam does not teach or suggest an active cushioning component wherein the active cushioning component is a bead, granule, particle or pellet, which

includes a cushioning component and a biologically active ingredient. Therefore, Applicants believe that claim 1 is patentable over Anaebonam.

Additionally, claims 2-10 depend from claim 1 and include all the recitations of claim 1. Thus, Applicants believe that claims 2-10 are also patentable over Anaebonam. Therefore, Applicants respectfully request that this rejection be withdrawn and claims 1-10 be allowed.

III. CLAIM REJECTION UNDER 35 U.S.C. § 103(a)

A. Claims 3 and 4 Are Patentable Over Habib.

Claims 3 and 4 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Habib. Applicants disagree and respectfully request that this rejection be withdrawn and claims 3 and 4 be allowed. Claims 3 and 4 depend from claim 1 and include all the recitations of claim 1. For the reasons discussed above, Applicants believe that claim 1 is patentable over Habib. Therefore, Applicants believe claims 3 and 4 are also patentable in view of Habib and respectfully request that this rejection be withdrawn.

IV. CONCLUSION

Since all claim rejections are believed to be overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with the Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

Respectfully submitted,

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